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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/701,868	12/05/2000	Kenneth C. Gross	0066.99	9165

7590

06/03/2003

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EXAMINER

COLLINS, CYNTHIA E

ART UNIT

PAPER NUMBER

1638

8

DATE MAILED: 06/03/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/701,868

Applicant(s)

GROSS ET AL.

Examiner

Cynthia Collins

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 04 March 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-12 and 14-32 is/are pending in the application.
- 4a) Of the above claim(s) 5-7,9-11,19-21,23-25 and 27-32 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-4,8,12,14-18,22 and 26 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- |                                                                                              |                                                                             |
|----------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                             | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____                                    |

### **DETAILED ACTION**

The Amendment filed March 4, 2003, paper no. 7, has been entered.

Claim 13 is cancelled.

Claims 1, 2, 3, 4, 8, 12, 14, 18, 22 and 26 are newly amended.

Claims 1-12 and 14-32 are pending.

Claims 5-7, 9-11, 19-21, 23-25 and 27-32 are withdrawn from consideration.

Claims 1-4, 8, 12, 14-18, 22 and 26 are examined on the merits in the instant office action.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

All previous objections and rejections not set forth below have been withdrawn.

### ***Claim Rejections - 35 USC § 112***

Claims 1-4, 8, 12-18, 22 and 26 remain rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention, for the reasons of record set forth in the office action mailed August 27, 2002.

Applicant's arguments filed March 4, 2003, have been fully considered but they are not persuasive.

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Applicant argues that GenBank accessions are sequences, not biological deposits, and that the claims have been amended to reflect this. Applicant also points out that the specification at page 10 indicates that the DNA sequence of the exemplary  $\beta$ -galactosidase II cDNA of the invention, determined from cDNA clone pZBG2-1-4, is recorded in GenBank as accession AF020390. Applicant also points out that the entire GenBank sequence has been disclosed and is publicly available, such that the claims are fully enabled (reply pages 8-9).

First, nucleic acid sequences such as plasmids and vectors are among those materials that can constitute a biological deposit (see for example MPEP 2403.01). Second, the rejection is maintained because the claims do not recite that SEQ ID NO:11 is the cDNA contained in GenBank Accession No. AF020390. Also, due to the recitation of "about" in the claims, it is unclear exactly what sequence is in GenBank Accession No. AF020390. Applicant may consider deleting the GenBank recitation from the claims in order to obviate the rejection.

Claims 1, 4 and 22, and claims 2, 3, 8, 12, 14-18 and 26 dependent thereon, remain rejected under 35 U.S.C. 112, second paragraph, as being indefinite are indefinite in the recitation of "polypeptide having the amino acid sequence at about position 24 to about position 724 of the sequence of SEQ NO:11", for the reasons of record set forth in the office action mailed August 27, 2002.

Applicant's arguments filed March 4, 2003, have been fully considered but they are not persuasive.

Applicant states that the native mature protein occurs at positions 24 through 274 of the complete protein, but, as discussed at pages 14-15 of the specification, cleavage of a secreted

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protein is not entirely uniform, such that additional amino acids may occur at either end.

Applicants also point out that the art teaches that additional amino acids do not interfere with enzyme function or activity. (reply pages 9-10).

The Office maintains that the metes and bounds of the claim are unclear, notwithstanding the fact that cleavage of a secreted protein is not entirely uniform and the additional amino acids do not interfere with enzyme function or activity. The amino acid sequence set forth in SEQ ID NO:11 is 724 amino acids in length. It is unclear how many of the 23 amino acids preceding amino acid 24 and/or how many of the 450 amino acids succeeding amino acid 274 would be present in the mature tomato  $\beta$ -galactosidase II set forth in the claims. Furthermore, pages 14-15 of the specification do not further clarify the metes and bounds, as pages 14-15 of the specification provide only that the not entirely uniform cleavage of the secreted protein results in "two or more mature species of the protein".

### ***Claim Rejections - 35 USC § 101***

Claims 1-4, 8, 12-18, 22 and 26 remain rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific asserted utility or a well established utility, for the reasons of record set forth in the office action mailed August 27, 2002. Claims 1-4, 8, 12-18, 22 and 26 also remain rejected under 35 U.S.C. 112, first paragraph, for the reasons of record set forth in the office action mailed August 27, 2002.

Applicant's arguments filed March 4, 2003, have been fully considered but they are not persuasive.

Applicant argues that the most important utility is the use of the TBG4 sequence in an antisense construct for transformation into tomato to increase fruit ripeness, and that the usefulness of the invention is described in the art. Applicant also argues that the use of antisense constructs is a well-established procedure within the level of skill in the art, and is supported by the disclosure (reply pages 11-12).

Applicant's arguments are not commensurate in scope with the claims. The claims are not directed to constructs that have an antisense function. The claims are directed to isolated nucleic acid molecules having a nucleotide sequence at least 95% identical to a sequence encoding a tomato  $\beta$ -galactosidase II polypeptide, and polynucleotides that hybridize to such nucleic acid molecules. Although the claims recite that the isolated nucleic acid molecules comprise a polynucleotide having structural features in common with nucleotide sequences encoding the amino acid sequence of SEQ ID NO:11, the claims do not recite any specific function for polynucleotides or for the polypeptide encoded by them. Absent a specific function, the claimed polynucleotides lack utility.

### ***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period

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will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

***Remarks***

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cynthia Collins whose telephone number is (703) 605-1210. The examiner can normally be reached on Monday-Friday 8:45 AM -5:15 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on (703) 306-3218. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

CC  
June 1, 2003

*Phuong Bui*  
PHUONG T. BUI  
PRIMARY EXAMINER 6/2/03